FIOR & GENTZ

Instructions for Use for Qualified Specialists in Orthopaedic Technology System Knee Joint

EN

NEURO HiTRONIC

NEURO HiTRONIC

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1. Information

These instructions for use are addressed to qualified specialists in orthopaedic technology and do not contain any notes about dangers which are obvious to them. To achieve maximum safety, please instruct the patient and/or care team in the use and maintenance of the product.

2. Safety Instructions

2.1 Classification of the Safety Instructions

⚠ DANGER	Important information about a possible dangerous situation which, if not avoided, leads to death or irreversible injuries.
⚠ WARNING	Important information about a possible dangerous situation which, if not avoided, leads to reversible injuries that need medical treatment.
⚠ CAUTION	Important information about a possible dangerous situation which, if not avoided, leads to light injuries that do not need medical treatment.
NOTICE	Important information about a possible situation which, if not avoided, leads to damage of the product.

All serious incidents according to Regulation (EU) 2017/745 which are related to the product have to be reported to the manufacturer and to the competent authority of the Member State in which the qualified specialist in orthopaedic technology and/or the patient is established.

2.2 All Instructions for a Safe Handling of the System Knee Joint

⚠ DANGER

Potential Traffic Accident Due to Limited Driving Ability
Advise the patient to gather information about all safety and security issues before driving a motor vehicle with orthosis. The patient should be able to drive a motor vehicle safely.

⚠ WARNING

Jeopardising the Therapy Goal by Not Providing the Necessary Free Movement
Check if the system joint moves freely in order to avoid restrictions of the joint function. Use suitable sliding washers according to the information in these instructions for use.

⚠ WARNING

Risk of Falling Due to Improper Processing
Process the system joint according to the information in these instructions for use. Deviating processing and modifications of the system joint require the written consent of the manufacturer.

⚠ WARNING

Risk of Falling Due to Permanent Higher Load
If patient data has changed (e.g. due to weight gain, growth or increased activity), recalculate the expected load on the system joint, plan the treatment again and, if necessary, produce a new orthosis.

⚠ WARNING

Risk of Falling Due to Improper Processing
Always mount the system knee joint to an orthosis with a system ankle joint in order to avoid joint dysfunction. This also applies in case of anatomical stiffening in the ankle joint.

⚠ WARNING

Risk of Falling Due to Improper Processing
During joint assembly, make sure that the roller of the roll unit is aligned parallel to the flexion stop disc before mounting the cover plate.

⚠ WARNING

Risk of Falling Due to Incorrectly Selected System Components
Make sure that the system joint and the system components are not overloaded and are functionally adapted to the requirements and needs of the patient in order to avoid joint dysfunction.

⚠ WARNING

Risk of Falling Due to Loosened Screws
Mount the cover plate to the system joint according to the assembly instructions in these instructions for use. Secure the screws with the specified torque and the corresponding adhesive and make sure that no sliding washers are damaged in the process.

⚠ WARNING

Risk of Falling Due to Use of Unauthorised Accessories
Use only the accessories specified or supplied by the manufacturer (power supply unit, charging cable) in order to avoid increased electromagnetic emissions and reduced electromagnetic immunity of the knee joint system.

⚠ WARNING

Risk of Falling Due to Improper Handling
Inform the patient about the correct use of the system joint and the **integrated electronics**, especially with regard to excessive mechanical load (e.g. due to sports, increased activity level or weight gain), and about not immersing the system joint in water. The electronic system components are only protected from splashing water on all sides. Also inform the patient that the system joint may only be demounted and maintained by a qualified specialist in orthopaedic technology. Any handling of the system joint and the orthosis by the patient that goes beyond the tasks described in the instructions for use for patients is not permitted.

⚠ WARNING

Risk of Falling Due to Improper Shoe/Wrong Shoe Pitch
Advise the patient to wear a shoe to which the orthosis is adjusted in order to avoid joint dysfunction in Auto mode.

⚠ WARNING

Risk of Falling Due to Improper Handling of the Orthosis
Make sure that the patient is able to handle their orthosis. Recommend a physiotherapeutic gait re-education, if necessary, and explain to them the system joint's particularities.

⚠ WARNING

Risk of Falling Due to Unintentional Performing of the Gesture
The use of gestures reduces the safety when using the orthosis. Only activate the gesture for sitting down in Auto mode if your patient is physically fit so that they do not fall if the gesture is performed unintentionally. Also advise them to be particularly careful when lifting heavier objects, as this movement could unintentionally trigger a gesture.

⚠ WARNING

Risk of Falling Due to Electromagnetic Interference
Do not use the knee joint system in close proximity to or stacked with other portable RF communication devices in order to avoid impairing the function of the knee joint system. If such use is necessary, observe the knee joint system and other portable RF communication devices in use to ensure that they function normally.

⚠ WARNING

Risk of Falling Due to Electromagnetic Interference
Use portable RF communication devices (including peripherals such as antenna cables and external antennas) at a safety distance of at least 30cm from all components of the knee joint system to avoid impairing the function of the knee joint system. If use at a distance of less than 30cm is necessary, observe the knee joint system during use to ensure that it functions normally. Also note the safety distances for RF communication devices specified in these instructions for use (see paragraph 31.6).

⚠ WARNING

Risk of Falling Due to Security Gaps in the Software
Carry out regular updates for your mobile device. Make sure that your **Expert** app and the operating system of your mobile device are always working with the latest version.

⚠ WARNING

Risk of Falling Due to Low Air Pressure
Set the air pressure to a minimum of 4 bar and a maximum of 5 bar in order to avoid joint dysfunction.

⚠ WARNING

Damage to the Anatomical Joint Due to Incorrect Position of the Joint's Mechanical Pivot Point
Determine the joint's mechanical pivot points correctly in order to avoid a permanent incorrect load on the anatomical joint. Please refer to the online tutorials on the FIOR & GENTZ website or contact Technical Support.

⚠ WARNING

Breakage of the System Joint Due to Lack of System Anchor
Use a system anchor when producing the orthosis in order to ensure a secure integration of the system joint into the laminate. The system joint can break if it is integrated without a system anchor.

⚠ WARNING

Risk of Electric Shock Due to Improper Handling
Only use the supplied accessories to avoid electric shock and damage to the knee joint system.

⚠ WARNING

Risk of Injury Due to Improper Handling of the Controller or Remote Control
Use the controller and the remote control as described in these instructions for use. The controller is a sensitive electronic device with an integrated lithium-polymer battery. Pay particular attention to:
- not wearing the orthosis during the battery charging process,
- avoiding contact with strong heat or fire,
- not charging the controller under direct sunlight, and
- not opening the controller or the remote control.

⚠ WARNING

Risk of Injury Due to Improper Handling of the System Joint
When using the system joint, an opening is formed between the joint's upper and lower part, in which clothing or skin could get caught. Please inform the patient of this risk.

NOTICE

Limitation of the Joint Function Due to Improper Processing
Errors in processing can impair the joint function. Pay particular attention to:
- correctly connecting the system side bar/system anchor with the system case in accordance with the production technique;
- not tempering the orthosis when the functional unit and controller are mounted,
- greasing the joint components only **slightly** and
- adhering to the maintenance intervals.

NOTICE

Limitation of the Joint Function Due to Improper Dirt Removal
Inform the patient on how to properly remove dirt from the orthosis and the system joint.

NOTICE

Limitation of the Joint Function Due to Lack of Maintenance
Respect the specified maintenance intervals in order to avoid joint dysfunction. Also inform the patient about the maintenance appointments to be respected. Enter the next maintenance appointment in the orthosis service passport of the patient.

NOTICE

Damage to the Controller Due to Improper Handling
Use the controller as described in these instructions for use. In particular, please ensure that the controller:
- is used only with the provided charging cable and power supply unit, and
- is only used at ambient temperatures from -10°C to +40°C.

NOTICE

Damage to the System Joint Due to Improper Handling of the Functional Unit
Do not open the functional unit. Do not remove any screws that are sealed with blind plugs labelled "SEAL" or any safety screws.

Advise the patient to contact the manufacturer in case of problems with the system joint and potentially occurring allergic reactions. You can find the manufacturer's contact data on the back page of these instructions for use.

3. Use

3.1 Intended Use

The **NEURO HiTRONIC** knee joint system including system knee joint and controller must be used exclusively for the orthotic treatment of the lower extremity. The system joint provides stance phase control and is only allowed to be used for producing a KAFO. Every system joint influences the orthosis' function and thus also the function of the leg. The system joint may only be used for one fitting and must not be reused.

The knee joint system is equipped with **Bluetooth®** technology. With the **Expert** app you can adjust orthoses that are equipped with the **NEURO HiTRONIC** system knee joint.

3.2 Indication

The indications for the treatment with an orthosis for the lower extremity are insecurities when standing and walking that lead to a pathological gait. This can be caused, for example, by paralyses, structurally conditioned deformities/malfunctions or as a result of neurological disorders (such as stroke or PAD), physical trauma and/or surgery.

The physical conditions of the patient, such as muscle strength or activity level, are crucial for the orthotic treatment. An evaluation regarding the safe handling of the orthosis by the patient must be carried out.

3.3 Contraindication

The system joint is not suitable for treatments that were not described in paragraph 3.2, such as a treatment of the upper extremity or a treatment with a prosthesis or ortho-prosthesis, for example after amputations of leg segments.

3.4 Qualification

The system joint must only be handled by a qualified specialist in orthopaedic technology.

3.5 Application

All FIOR & GENTZ system joints were developed for everyday life activities such as standing and walking. Extreme impact stress, which occurs for example during long jump, climbing, parachuting and football, is excluded. The system joint can be used at temperatures of -10°C to +40°C.

3.6 Combination Possibilities with Other System Joints

The **NEURO HiTRONIC** system knee joint must be combined with a system ankle joint from the FIOR & GENTZ product range. The **NEURO VARIO** system knee joint can be used as a supporting joint.

We recommend that you use the Orthosis Configurator when selecting all system components for your orthosis and follow the recommendations of the configuration result.

4. Joint Functions

The **NEURO HiTRONIC** is a microprocessor-controlled, automatic system knee joint and provides four joint functions:

- basic function in delivery status in Auto mode
- alternative function in Lock mode
- alternative function in Free mode
- alternative function in permanent unlocking

The essential performance features of the automatic electronic system joint are to remain unlocked in Free mode and locked in Lock mode, as well as to lock or unlock at the right moment in Auto mode.

The system knee joint is preassembled at an angle of 5°, corresponding to a physiological knee joint angle. By exchanging the 5° flexion stop disc for a 0° or a 10° flexion stop disc and the 5° extension stop for a 0° or a 10° extension stop, the joint angle can be changed by 5° in the direction of flexion or extension.

If electromagnetic interference occurs, the automatic knee joint system does not function as described in these instructions for use. Read the safety instructions before using the knee joint system to avoid problems.

4.1 Safe Handling of the Joint Functions

Standing Up From a Seated Position

Before the patient stands up, the **NEURO HiTRONIC** system knee joint must be set to Free mode. Once standing securely, the mode can be switched to Auto or Lock mode.

Stance Phase Control

The system joint ensures the continuously variable stance phase in a knee angle of 0° (5°) to 45°. Stance phase control occurs between 45° and 50° contingent upon the load. If the load limit is exceeded, an overload protection takes effect. It is comparable to an electric fuse. If the overload protection is triggered, this may result in deformation of the roll holder and possibly its fracture. In such a case, the roll unit must be exchanged.

4.2 Basic Function in Auto Mode

The controller has motion sensors that detect the movement and position of the lower leg. The controller ensures that the hydraulic functional unit locks/unlocks the system joint in the respective gait phases.

Stance

When the patient is standing with the orthosis (fig. 1) or when they do not finish their step in stance phase, the system knee joint locks, as no movement is registered.

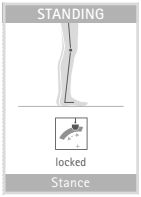


fig. 1

Gait

When walking, the system joint locks/unlocks as follows: the system joint is locked in the direction of flexion from mid swing to mid stance. In the gait phases from terminal stance to initial swing, the system joint is unlocked and is therefore free moving (fig. 2).

The locking/unlocking moment can be fine adjusted with the **Expert** app.

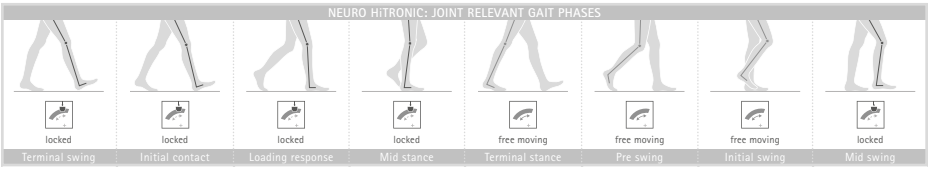


fig. 2

In the free moving phases terminal stance and pre swing, the system knee joint is not secured electronically in order to prepare the knee flexion for pre swing:
- In terminal stance, securing against knee flexion takes place via the levering back extension moment of the forefoot lever.
- If, contrary to expectations, weight is put on the leg with orthosis in pre swing when the step is interrupted in this phase, the system knee joint will not lock. Explain this situation to the patient and, if necessary, train with them.

If the free moving phase initial swing is unexpectedly interrupted, the system knee joint will lock safely.

4.3 Alternative Function in Lock Mode

In Lock mode, the **NEURO HiTRONIC** system knee joint is permanently mechanically locked in a defined extension position.

4.4 Alternative Function in Free Mode

In Free mode, the **NEURO HiTRONIC** system knee joint is unlocked and free moving up to a defined extension position. When the patient is standing with the orthosis, the stance phase control is achieved by means of the integrated posterior offset (fig. 3) and the patient's remaining function of the knee and hip extension muscles.

The system joint must be brought in extension within two seconds of activating Free mode using the remote control/app. Otherwise, the app or the controller will indicate that the system joint is in Free mode, even though it remains mechanically locked. The system joint cannot be unlocked under flexion load.

fig. 3

4.5 Alternative Function in Permanent Unlocking

The **NEURO HiTRONIC** system knee joint can be permanently unlocked mechanically with a rotary switch, for example for activities such as riding a bicycle. In this mode it is guaranteed that the system knee joint does not lock unintentionally. To do so, take a seat and unlock the system joint manually using the rotary switch below the system joint, by pressing in the rotary switch and turning it in the direction of the symbol.

In order to save energy, you can then press the Lock button with the remote control/**User** app. The system knee joint remains unlocked even if you select another mode (e.g. Auto) with the remote control/app. In order to change the system joint's mode again with the remote control/app, turn the rotary switch in the direction of the symbol (fig. 4).

The mechanical, permanent unlocking via the rotary switch cancels all electronic commands from the remote control/app.

5. Rotary Switch

There is a rotary switch below the system joint (fig. 4). The three symbols show what happens if the rotary switch is turned in their respective direction. The arrows below show how the rotary switch should be controlled in order to select a symbol.

Symbol	Action	Meaning
	Turn the rotary switch in the direction of the symbol.	The system joint is operated from the remote control/app.
	Turn the rotary switch in the centre and press in.	The system joint is mechanically unlocked as long as the rotary switch is pressed in. As soon as it is released, the system joint will be operated once again from the remote control/app.
	Press in the rotary switch and turn it in the direction of the symbol.	The system joint is now in permanent, mechanical unlocking (see paragraph 4.5).

fig. 4

6. NEURO HiTRONIC Knee Joint System

The knee joint system is equipped with Bluetooth technology* and consists of the following components (fig. 5):

1. **system knee joint**
2. **controller**
3. **remote control** for the patient including **charging cable with power supply unit** and **User** app
4. **Expert** app for qualified specialists in orthopaedic technology

The system knee joint and the controller are built into the patient's orthosis. In order to put the orthosis into operation and adjust it, you need the **Expert** app. The app must be activated once using the code generator for the **Expert** app on the FIOR & GENTZ website. The patient needs the remote control to operate the orthosis. In addition, the **User** app can also be used.

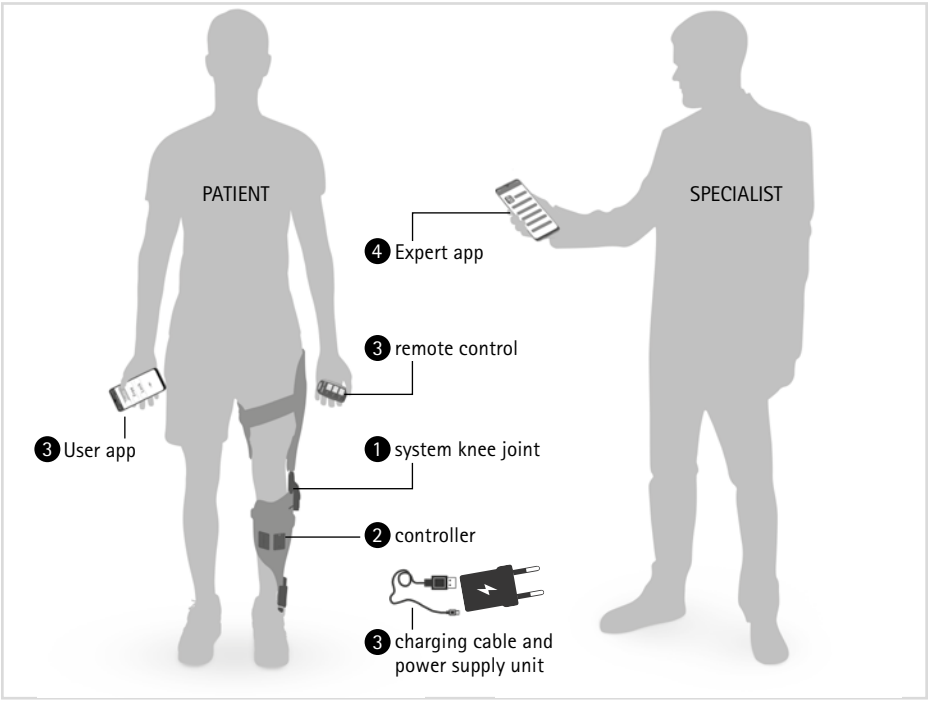


fig. 5

* The Bluetooth word mark and logos are registered trademarks of Bluetooth SIG, Inc. and any use of such marks by FIOR & GENTZ is under license.

For the production of a KAFO with the **NEURO HiTRONIC** you need, in addition to the system knee joint, a controller set, a remote control set, a maintenance set, a connection cable set as well as a tool set. The lamination dummy for the controller included in the tool set is reusable. The maintenance set is included in the scope of delivery of the system joint. Use the pump set included in the tool set to check the pressure of the system joint's pneumatic spring before handing over the orthosis and during each maintenance, and adjust it if necessary.

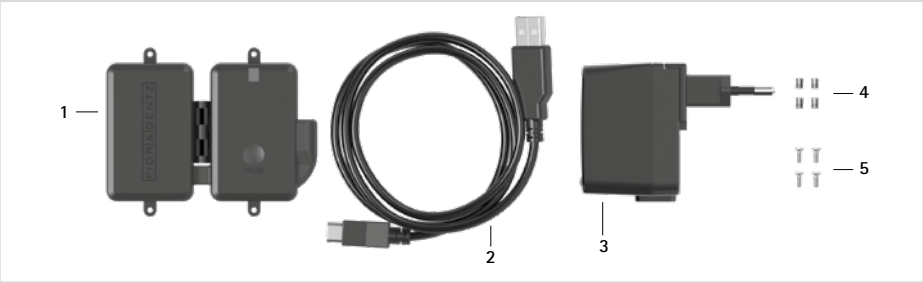


fig. 6

Controller Set (SL3860-S)				
Item	**Article Number**	**Description**	**Unit**	**Quantity** Unilateral
1	ET3860	controller with Bluetooth with lithium-polymer battery	pce.	1
2	ET0710-01	charging cable for controller, 1m	pce.	1
3	ET0780-01	power supply unit incl. primary adapters for Europe, USA/Japan, Great Britain, Australia	pce.	1
4	VE0831-A3	thread insert	pce.	4
5	SC1302-L06	countersunk flat head screw, cross recessed H	pce.	4

Please note that the charging cable and power supply unit are not part of the medical device.

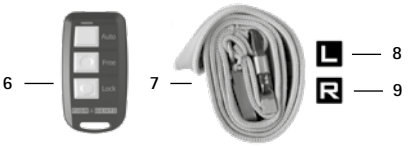


fig. 7

Remote Control Set (SL3860-P)				
Item	Article Number	Description	Unit	Quantity Unilateral
6	ET3840-P	remote control with Bluetooth for the patient	pce.	1
7	PR4000	lanyard FIOR & GENTZ	pce.	1
8	HE3800-SK/L	letter sticker L for remote control, left leg	pce.	1
9	HE3800-SK/R	letter sticker R for remote control, right leg	pce.	1

fig. 8

Maintenance Set (SL3005-6M)*				
Item	Article Number	Description	Unit	Quantity Unilateral
10	SC1404-L10	countersunk flat head screw with hexalobular socket	pce.	2
11	SC1405-L14	countersunk flat head screw with hexalobular socket	pce.	1
12	SC1406-L14	countersunk flat head screw with hexalobular socket (axle screw)	pce.	1
13	SL0355-01	guide piece	pce.	1
14	SL0355-11	roll unit	pce.	1
15	SL0355-12	air filter	pce.	1
16	VE3771-012/26	O-ring damper	pce.	2

* The maintenance set is included in the scope of delivery of the system joint.

not in combination with a NEURO HiSWING R+

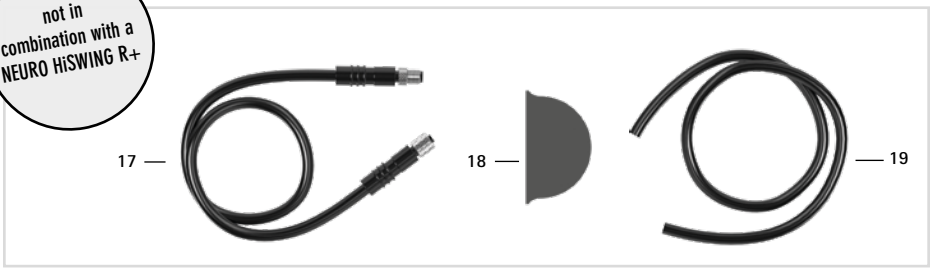


fig. 9

Connection Cable Set NEURO HiTRONIC (SL3860-K)				
Item	Article Number	Description	Unit	Quantity Unilateral
17	ET0711-01	connection cable for functional unit NEURO HiTRONIC, 300mm	pce.	1
18	ET0971-1	lamination dummy for cable length compensation	pce.	1
19	SL0935-14	lamination dummy for connection cable for NEURO HiTRONIC functional unit, 190mm	pce.	1

only in combination with a NEURO HiSWING R+

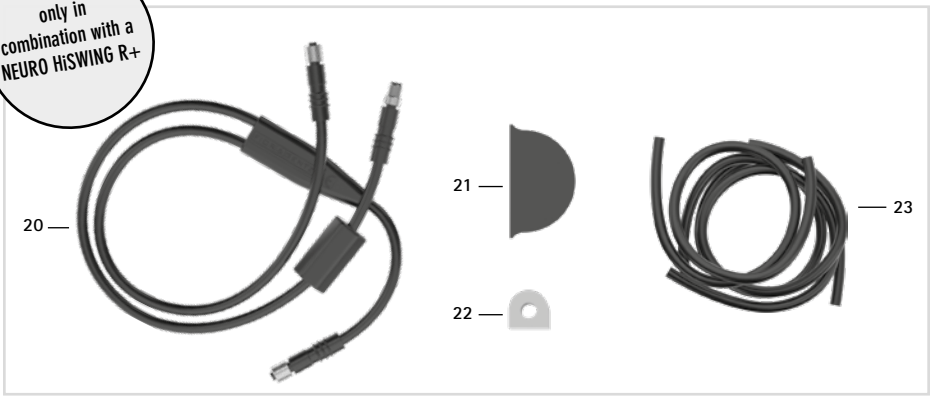


fig. 10

Connection Cable Set NEURO HiSWING R+, NEURO HiTRONIC (SL3860-K/4)				
Item	Article Number	Description	Unit	Quantity Unilateral
20	ET0713-02	connection cable for functional unit NEURO HiTRONIC and NEURO HiSWING R+, 660mm	pce.	1
21	ET0971-1	lamination dummy for cable length compensation	pce.	3
22	ET0972-3	lamination dummy for connection cable for functional unit	pce.	1

Connection Cable Set NEURO HiSWING R+, NEURO HiTRONIC (SL3860-K/4)				
Item	Article Number	Description	Unit	Quantity Unilateral
23	SH0985-15	lamination dummy for connection cable for NEURO HiSWING R+ functional unit, 270mm	pce.	1
23	SH0985-16	lamination dummy for connection cable for controller, 140mm	pce.	1
23	SL0935-17	lamination dummy for connection cable for NEURO HiTRONIC functional unit, 190mm	pce.	1

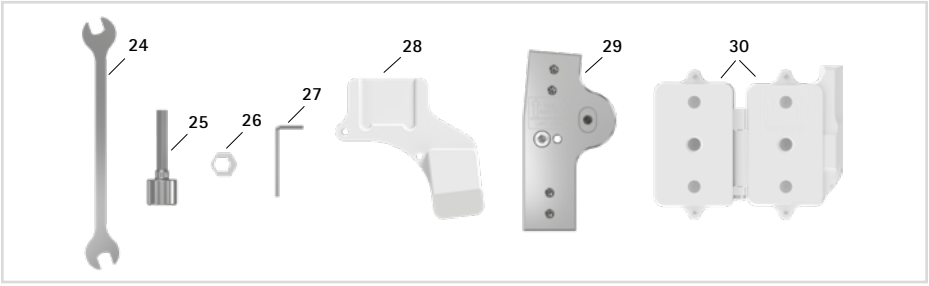


fig. 11

Tool Set for Assembly and Maintenance (SL3005-WZ)				
Item	Article Number	Description	Unit	Quantity Unilateral
24	WZ5018-0612	double open-end wrench, 6.5mm	pce.	1
25	WZ5602-A13	socket wrench insert, 13mm, 1/4"	pce.	1
26	WE3055-SL	adaptor for socket wrench insert	pce.	1
27	WZ5611-I20	hexagon key wrench, 2mm	pce.	1
28	SL0935-6	shaping dummy	pce.	1
29	PS3305-SL	side bar/anchor retainer	pce.	1
30	ET0935	lamination dummy for controller, two parts	pce.	1
31–34	SL3005-PS	pump set*	set	1

Tool Set for Maintenance (SL3055-WZ)				
Item	Article Number	Description	Unit	Quantity Unilateral
24	WZ5018-0612	double open-end wrench, 6.5mm	pce.	1
25	WZ5602-A13	socket wrench insert, 13mm, 1/4"	pce.	1
26	WE3055-SL	adaptor for socket wrench insert	pce.	1
27	WZ5611-I20	hexagon key wrench, 2mm	pce.	1
31–34	SL3005-PS	pump set*	pce.	1

* The components of the pump set are listed in the table below.

fig. 12

Pump Set (SL3005-PS)				
Item	Article Number	Description	Unit	Quantity Unilateral
31	WZ0035-SL	air pump	pce.	1
32	WE0335-SL	adaptor for air pump and system joint	pce.	1
33	WE3065-SL/3	bit for safety screw	pce.	1
34	WZ0035-SL/1	needle for pressure relief	pce.	1

You can find more information on special work steps that must be observed when producing an orthosis with the **NEURO HiTRONIC** system knee joint, such as the placement of dummies as well as the specifics of reinforcement, in the corresponding online tutorial (see QR code, fig. 13) on the FIOR & GENTZ website.

fig. 13

7. Scope of Delivery of the System Knee Joint

Description	Quantity
NEURO HiTRONIC system knee joint (fig. 14)	1
orthosis joint grease, 3g (without figure)	1
maintenance set (fig. 8)	1

fig. 14

8. Load

The actual load on the system joints is based on the relevant patient data. The load and the appropriate system components can be determined by using the Orthosis Configurator. We recommend that you use the system components determined by the Orthosis Configurator when producing an orthosis and mind the recommended production technique. You will find information on the production techniques in the section “Online Tutorials” on the FIOR & GENTZ website.

9. Tools for Assembling the System Joint

Tool	System Width 20mm
T8 hexalobular screwdriver/bit	x
T20 hexalobular screwdriver/bit	x
torque screwdriver, 1–6Nm	x
slotted screwdriver, 3–4mm blade width	x
6.5mm double open-end wrench	x
13mm socket wrench insert, ¼"	x
adaptor for socket wrench insert	x
hexagon key wrench, 2mm	x
twist drill, 3.2mm	x
PH0 cross-recessed screwdriver	x

10. Functional Unit

The functional unit includes the hydraulic system with hydraulic oil. The functional unit is delivered fully assembled. The functional unit may not be opened. Do not remove any screws that are sealed with blind plugs labelled "SEAL" or the safety screw of the hydraulic system, as this will invalidate the warranty (fig. 15). The sealed screws may only be removed when the functional unit is disposed of.

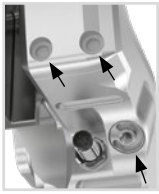


fig. 15

Only adjust the plunger guide ring (fig. 28) when the functional unit is mounted onto the joint's lower part to prevent damage to the functional unit.

11. Mounting the System Joint

The system joint is delivered fully assembled. All functions are checked beforehand. You have to partly disassemble the system joint for mounting onto the orthosis and for maintenance. To ensure an optimal functioning, follow the assembly instructions below. Secure all screws with the torque specified in paragraph 11.7.

You can find more information on the assembly in the online tutorial **Joint Assembly NEURO HiTRONIC** (see QR code, fig. 16) on the FIOR & GENTZ website.

fig. 16

The hydraulic system of the functional unit must not be opened.

When mounting the system joint, mind the correct basic alignment of the orthosis as it is essential for the later function of the orthosis. You can find more information on this in the online tutorial **KAFO Alignment Guidelines** (see QR code, fig. 17) on the FIOR & GENTZ website.

fig. 17

Only use the FIOR & GENTZ orthosis joint grease to grease the system components.

11.1 Mounting the Joint's Upper and Lower Part

1 Adhere the joint according to the online tutorial **KAFO in Anchor Lamination Technique** (see QR code, fig. 18).

fig. 18

11.2 Preparation of the Joint's Upper Part

1 Place the flexion stop disc on the joint's upper part (fig. 19).

fig. 19

11.3 Preparation of the Joint's Lower Part

1 Before assembly, use LOCTITE® 7063 Super Clean to clean the threads of the joint's lower part and of the bearing nut. Allow the threads to air-dry for 10 minutes.
2 Insert the extension stop and the O-ring damper into the joint's lower part (fig. 20).
3 Loosen the screws (S1 and S2) on the back of the functional unit (fig. 21).
4 Place the functional unit on the joint's lower part (fig. 22).

fig. 20

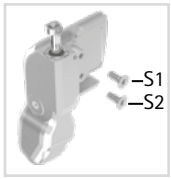


fig. 21

11.4 Preparation of the Cover Plate

1 Insert the guide piece in the cover plate (fig. 23).
2 Apply spray adhesive on one side of a sliding washer and adhere it to the cover plate (fig. 23).
3 Grease the other side **slightly** with orthosis joint grease.

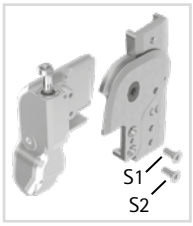


fig. 22

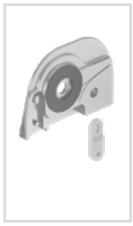


fig. 23

11.5 Mounting the System Joint

Make sure not to damage the sliding washer during assembly. Jammed sliding washer particles can cause lateral play in the system joint.

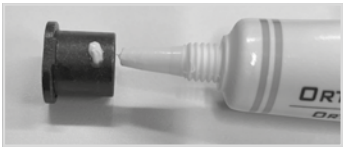


fig. 24

1 Grease the axle bore and the sliding surfaces of the bearing nut **with a drop** of orthosis joint grease (fig. 24).
2 Place the bearing nut in the joint's lower part (fig. 25).
3 **Slightly** grease the second sliding washer on both sides with orthosis joint grease and place it in the joint's lower part above the bearing nut.
4 Attach the joint's upper part with the flexion stop disc to the joint's lower part above the bearing nut (fig. 26). Should the functional unit's plunger protrude too far, set the rotary switch to the icon and press in the plunger until the joint's upper part fits. Next, you must adjust the plunger guide ring (see step 10).
5 Mount the cover plate and screw in the first countersunk flat head screw (axle screw, S3; fig. 27).
6 Screw in the second countersunk flat head screw (S4; fig. 27).
7 Screw in the screws for the functional unit into the joint's lower part from behind, in order to screw it together with the functional unit (fig. 22).
8 Press the rotary switch (fig. 4) in order to permanently unlock the system joint.

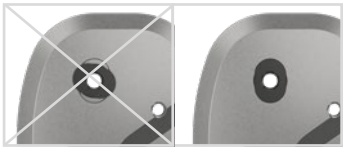


fig. 25

fig. 26

fig. 27

9 Carefully unscrew the S5 screw (fig. 28) using the hexagon key wrench (fig. 29).
10 Adjust the plunger guide ring (fig. 28) of the functional unit using a slotted screwdriver. When the upper part has made slight contact with the O-ring dampers, there should be a minimum gap between the roll unit and the flexion stop disc. If the plunger guide ring has been unscrewed too much, the system joint will not unlock. If screwed in too far, some play will arise when the system joint is locked.
11 Screw in the screw (S5; fig. 28) slightly with the hexagon key wrench until the plunger guide ring no longer moves (fig. 29).

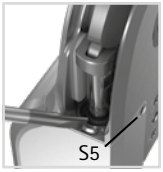


fig. 28

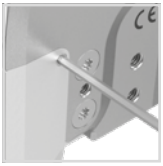


fig. 29

Do not tighten the screw (S5; fig. 28) more than necessary, as the plunger will otherwise not be able to move upwards from the lower position.

11.6 Checking the Free Movement

Tighten the screws for the functional unit and the cover plate with the appropriate torque (see paragraph 11.7). Check if the system joint moves freely. If the system joint runs with lateral play, mount the next thicker sliding washer. If it does not move freely (it is jammed), mount the next thinner sliding washer.

11.7 Securing the Screws

The screws are secured after the orthosis has been produced and tried on and before it is handed over to the patient.

1 Loosen the screws for the cover plate (fig. 27) after checking the free movement and remove them from the cover plate.
2 Apply a small drop of LOCTITE® 243 medium strength to the thread of the screws.
3 Secure the screws for the functional unit and the cover plate (fig. 22 and 27) with the torque corresponding to the system width.
4 Let the adhesive harden (final strength after approx. 24 hours).

Screws for the Functional Unit and Cover Plate	System Width 20mm
countersunk flat head screws for the functional unit (S1 and S2)	3Nm
countersunk flat head screw for the cover plate (axle screw, S3)	4Nm
countersunk flat head screw for the cover plate (S4)	4Nm

The screws for the cover plate are not secured with the necessary torque at delivery. You can also find information on the torque in the openings of the cover plate.

12. Adjustable Air Pressure

Use the pump set included in the tool set to check the pressure of the system joint's pneumatic spring before handing over the orthosis and during each maintenance, and adjust it if necessary. During longer storage periods, a drop in pressure may occur, causing small amounts of hydraulic oil to leak out. As long as the system joint is functioning correctly, this is not a cause for concern.

Some patients are not able to reach full knee extension at the end of terminal swing due to weak hip flexors and knee extensors. The pressure of the system knee joint's pneumatic spring can be adjusted using an air pump to optimise the system joint's extension assist during swing phase.

fig. 30

1 Unscrew the safety screw that covers the pneumatic spring valve using the bit for safety screw.
2 Carefully insert the needle for air pressure relief into the opening of the pneumatic spring valve (fig. 30), applying only light pressure. You will hear air escaping.
3 Screw in the adaptor for air pump and system joint (fig. 31) and connect the air pump.
4 Inflate the pneumatic spring to the required air pressure. If you have set the air pressure too high, remove the adaptor and repeat the procedure as described above from step 2 onwards. The pressure relief button on the air pump has no function for the system joint.

fig. 31

Set the air pressure to a minimum of 4 bar and a maximum of 5 bar (fig. 32) in order to avoid joint dysfunction. The ideal value is 4 bar and should only be increased if full extension is not achieved during swing phase. The higher the air pressure, the higher the extension assist.

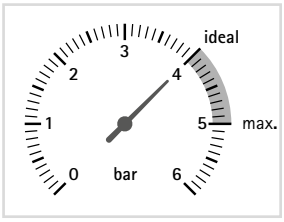


fig. 32

5 Then, secure the safety screw using the bit for safety screw and a torque of 1.5Nm.

The air pump display shows a drop in pressure as soon as you stop pumping. This drop only occurs in the area between the pneumatic spring valve and the air pump. Within the pneumatic spring, the last displayed maximum value is retained. For this reason, the pressure relief button on the pump has no effect on the system joint.

You can find more information on the adjustable air pressure in the corresponding function video (see QR code, fig. 33) on the FIOR & GENTZ website.

fig. 33

13. Connecting to the System Side Bar/System Anchor

The system side bar/system anchor must be connected to the system joint by adhering and screwing or screwing and wrapping in accordance with the production technique provided in the planning (fig. 34–36). You can find more information in the **Instructions for Use for Qualified Specialists in Orthopaedic Technology System Side Bars and System Anchors** (see QR code, fig. 37). You will find information on the production techniques in the section "Online Tutorials" on the FIOR & GENTZ website.

fig. 34

fig. 35

fig. 36

fig. 37

14. Notes on the Production of the Orthosis

You need a side bar/anchor retainer to produce the orthosis without having to laminate the system joint. This facilitates the production of the orthosis and prevents possible damage to the system joint during processing.

Make sure that the side bar/anchor retainer is aligned correctly during all work steps. Markings on the tool show where and how it must be aligned on the model (fig. 38).

fig. 38

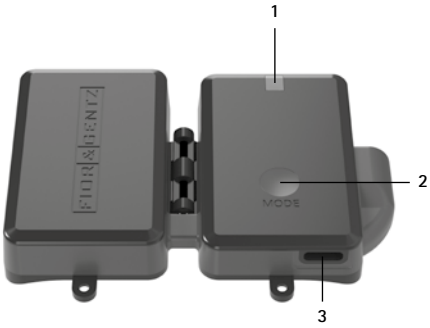
15. Conversion Options

An orthosis with a **NEURO HiTRONIC** system knee joint can be converted into an orthosis with a **NEURO TRONIC** or **NEURO MATIC** system knee joint by exchanging the system joint. To do so, please contact Technical Support.

16. Controller

The controller is mounted to the orthosis. It receives adjustments from the **Expert** app and commands from the remote control/**User** app, registers the patient's movements and controls the **NEURO HiTRONIC** system knee joint.

When producing the orthosis, ensure that the controller is positioned so that the charging port is at the bottom.

Controller with Integrated Lithium-Polymer Battery	Item	Description
	1	multicolour LED for battery charging, mode and Bluetooth connection
	2	MODE button
	3	charging port

For more information on mounting the controller to the orthosis, refer to the online tutorials on the FIOR & GENTZ website.

16.1 Cable Connection for the Controller and Functional Unit

Only tighten the knurled threaded bushings by hand. Do not use pliers to tighten the threaded bushings.

Before you mount the controller onto the orthosis, you must establish a connection to the functional unit of the system knee joint via a connection cable.

fig. 39

1 Insert the connection cable into the port on the functional unit (fig. 39) and tighten the knurled threaded bushing by hand.
2 Place the cable cover over the connecting point and affix it using the accompanying countersunk flat head screw (fig. 40).
3 Insert the connection cable into the port on the controller (fig. 41) and tighten the knurled threaded bushing by hand. A small gap remains visible.
4 Secure the controller to the orthosis shell using the accompanying countersunk flat head screws.

fig. 40

fig. 41

17. Functional Check of the Functional Unit

In order to check the function of the functional unit, proceed as follows:

1 Set the Free mode with the remote control. Try to flex the orthosis. The system joint should be unlocked and the orthosis should be able to move in the direction of flexion.
2 Set the Lock mode with the remote control. Try to flex the orthosis. The system joint should be locked and the orthosis should not be able to move in the direction of flexion.
3 Set the rotary switch on the system joint to Free. Position the orthosis in such a manner that you can see the plunger. Flex the system joint by 90° and quickly bring it into full extension. If the plunger moves too slowly upwards and loses contact with the flexion stop disc (fig. 42), use the air pump to increase the pressure of the pneumatic spring.

fig. 42

18. Checking the Orthosis' Basic Alignment

Make sure that the orthosis' alignment is correct before putting the orthosis into operation. You can then make further adjustments to the orthosis using the **Expert** app. You can find more information on the correct orthosis' alignment in the online tutorials **Checking the Orthosis' Alignment – Dynamically** (see QR code, fig. 43) and **Checking the Orthosis' Alignment – Statically** (see QR code, fig. 44) on the FIOR & GENTZ website, or on our YouTube channel.

fig. 43

On the Workbench

Regardless of the plantar flexion, automatic system knee joints require a systematic adjustment of the dorsiflexion stop for an optimal function of the orthosis. The dorsiflexion stop determines the moment the system knee joint unlocks during mid stance. Furthermore, it leads to an extension moment which is applied to the orthosis and the system knee joint, which is necessary to unlock the system knee joint.

fig. 44

Fix the foot piece of the orthosis firmly in the patient's shoe and put the orthosis on the workbench. The dorsiflexion stop of the system ankle joint must be adjusted in such a way that the line of gravity passes through the middle of the thigh shell and runs vertically downwards in front of the system ankle joint and between the ankle's pivot point and the rolling-off line.

Statically on the Patient

For checking the correct static alignment of the orthosis, the patient must wear the orthosis and stand upright with parallel feet. When viewed from the side, the line of gravity must run from the body's centre of gravity vertically downwards in front of the system ankle joint and between the ankle's pivot point and the rolling-off line. The course of the line of gravity at knee height results from the individual normal posture. Wearing the orthosis leads to deformation of soft tissue. This deformation causes the line of gravity to shift forward. Please consider this by readjusting the dorsiflexion stop, if necessary.

If the dorsiflexion stop is adjusted correctly, a lever is formed between the forefoot and lower leg (activation of the forefoot lever) which brings the patient into a stable balance (they are able to balance themselves) and applies the necessary knee extension moment.

Dynamically on the Patient

For checking the correct dynamic alignment of the orthosis, the patient must wear the orthosis and walk a few steps with it. The dorsiflexion stop must be adjusted in such a way that a heel lift can clearly be seen in terminal stance. The consequence is a lever between forefoot and lower leg which brings the patient into a stable balance and applies the necessary knee extension moment. If the heel does not lift, you must reduce the system ankle joint's range of motion in dorsiflexion.

19. Putting into Operation

19.1 Putting the **Expert** App into Operation

fig. 45

Download the app with your smartphone/tablet. Minimum requirements are Bluetooth 4.0 and Android 6.0 or iOS 12. Activate the app once using the code generator for the **Expert** app on the FIOR & GENTZ website. This ensures that patients cannot access the **Expert** app and change the orthosis' settings.

Carry out regular updates for your mobile device and enable automatic updates. Make sure that your **Expert** app and the operating system of your mobile device are always working with the latest version. If the manufacturer of your mobile device no longer offers updates to fix bugs or security gaps, it is advisable to switch to a newer device.

19.2 Connection between Controller and Remote Control

In order to connect the remote control to the controller, proceed as follows:

1 Press the MODE button on the controller. First, a short beep is emitted. Press and hold the button until a second, longer beep is emitted after about 6–10 seconds.
2 Press the Auto and Lock buttons on the remote control at the same time for about four seconds. The LED blinks orange.

The orthosis can only be controlled by the one remote control or app to which it is currently connected. Other remote controls/apps have no influence on the orthosis.

If the connection to the controller has been successful, the LED on the remote control blinks green. If establishing the connection has failed, it blinks red.

A remote control can also be connected to two controllers:

1 Press the MODE button on both controllers. First, a short beep is emitted. Press and hold the buttons until a second, longer beep is emitted after about 6–10 seconds.
2 Press the Auto and Lock buttons on the remote control at the same time for about four seconds. The LEDs light up.

If the connection to both controllers has been successful, the LED on the remote control blinks green twice. If the LED on the remote control blinks green only once, the remote control is only connected to one controller. In this case, repeat steps 1–2. If establishing the connection has failed, the LED blinks red.

19.3 Connection of Controller and **Expert** App

In order to adjust an orthosis with the app, Bluetooth must be permanently activated and the app must be opened in the foreground. Use the app menu and select the menu item **Pairing**. Follow the additional instructions in the app. The controller cannot communicate simultaneously with multiple **Expert** apps. If there is an active connection to the app, the blue LED on the controller will blink permanently. If you want to adjust the orthosis with the **Expert** app on a different mobile device, you must first close the app that is currently connected to the controller.

20. Adjustment Options with the Expert App

20.1 Selecting a Mode

You can select the available modes Auto, Free and Lock with the app. The mode is active when the respective mode is displayed with a green background.

20.2 Menu

In the menu you can set various adjustments for the orthosis. Follow the instructions in the app.

20.2.1 Pairing (Putting the Controller Into Operation)

In order to establish a connection between the controller and the app, use the app's menu and select the required menu item for a connection with one or two controller(s). Follow the additional instructions in the app.

20.2.2 Calibrate

In order for the motion sensors in the controller to detect the position of the lower leg, you have to calibrate the orthosis for a first functional test before fitting. Then, repeat the calibration process. Have the patient wear the orthosis when you calibrate again. Follow the instructions in the app.

20.2.3 Basic Position

Bring the leg with orthosis into the basic position and confirm this with the app. This step is important for performing the gestures (see paragraph 20.2.5.6).

20.2.4 General Settings

In this menu item you can make adjustments to the orthosis. To do so, follow the instructions in the app.

20.2.4.1 Mode Change

With this menu item, you can adapt the mode change settings of the controller, in order to make a mode change possible even while in motion. Usually, the patient changes the mode while at standstill. Changing the mode while the patient is in motion can endanger the patient's safety. If the patient nevertheless wants to change the mode while in motion, follow the instructions in the app.

20.2.4.2 Sound

In the sound settings, you can set the volume, tone and type of signal tone for the signal tones for training purposes or for the signal tones for gestures.

The signal tones for training purposes support the patient acoustically. When the patient exercises walking with the orthosis, the orthosis provides a tone signal if the signal tone is on. This signal indicates if the system joint is locked or free moving.

With the signal tones for gestures, a signal tone sounds after the controller has registered an executed gesture (see paragraph 20.2.5.6). After the patient has sat down and the system joint is locked again, another signal tone sounds.

For the tone, you can choose between two frequencies. This way, you can select a different tone for each controller/orthosis at a bilateral treatment.

20.2.5 System Knee Joint Settings

20.2.5.1 Mid Stance

With this menu item, you can fine adjust the time when the system knee joint unlocks in mid stance. Follow the instructions in the app.

Have the patient practise walking with the orthosis with the adjusted time of unlocking and adapt the settings again, if required.

20.2.5.2 Initial Swing

With this menu item, you can change the point in time when the system knee joint locks in initial swing.

In a physiological gait, knee flexion begins in pre swing and the final knee flexion is achieved in initial swing. The **NEURO HiTRONIC** system knee joint locks in the achieved knee flexion in initial swing. You can change the exact time of locking in initial swing with this menu item. Locking at a later point in time is particularly suitable for patients who have previously worn an orthosis with locked joints, as these patients often do not initiate knee flexion in pre swing, but in initial swing. The standard setting is optimised for a physiological gait.

20.2.5.3 Easier Unlocking

Here, you have the option to adjust the orthosis in a way that enables the system knee joint to unlock easier during rotation movements. This menu item is preset to 0, which applies to patients with a physiological rotation. Patients with unphysiological inward or outward rotation movements of the leg may experience problems with unlocking, making a harmonious gait difficult. In such a case, you can set easier unlocking with this menu item. Follow the instructions in the app. Inform yourself of situations in which this might make sense, as well as the process and safety-related aspects, in the **Expert** app.

Inform the patient of the changes involved in setting an easier unlocking. Make sure that the patient confirms in writing, on the back page of the instructions for use, that they have understood this process and the resulting consequences.

Please note that setting an easier unlocking leads to a reduction in stability, which makes it easier for the patient to fall. Only set an easier unlocking if it is necessary and instruct the patient accordingly.

20.2.5.4 First Step

With this menu item you can adjust the settings for the first step to facilitate walking. In the default setting, the detection of the first step is deactivated. This is the safest setting as the orthosis only unlocks in the second swing phase. For patients who feel very secure walking with their orthosis, the detection of the first step can be activated. In this case, we recommend that the patient makes the first step with the non-orthotically treated leg. During the second step, the controller detects the first swing phase of the treated leg and the system knee joint is automatically unlocked. This enables a physiological gait.

For patients who have both legs treated with orthoses, we recommend activating the detection of the first step for the orthosis with which the patient wants to take the second step. The first step is therefore taken with the orthosis in a locked state, which provides more stability.

For unilateral treatments where the patient feels insecure and takes pathological, slow steps, the detection of the first step should not be activated.

20.2.5.5 Using a Walker

With this menu item, you can optimise the locking/unlocking moment for patients using a walker. This setting should be activated for patients who only use the orthosis with the support of a walker and are under therapeutic supervision. For all other patients, this setting is not suitable.

20.2.5.6 Gestures

With this menu item, you can activate the gesture for sitting down in Auto mode. You have to carry out the first activation. Afterwards, the patient can switch the function off and on themselves. This gesture unlocks the system joint for a short time while in Auto mode so that the patient can sit down. To do so, the patient has to stand still in basic position for one second and then set down the affected leg with the heel and wait for another second. The system joint unlocks and the patient can sit down. The system joint locks as soon as the lower leg is put in a vertical position.

The use of gestures reduces the safety when using the orthosis. Only activate the gesture for sitting down in Auto mode if your patient is physically fit so that they do not fall if the gesture is performed unintentionally.

20.2.5.7 Gestures via Smartwatch

If the patient has an Apple Watch* or a Samsung** Watch, they can alternatively activate sitting down in Auto mode with the gestures via smartwatch. You can find further information under **Gestures via Smartwatch** on the FIOR & GENTZ website (see QR code, fig. 46).

fig. 46

* Apple Watch is a trademark of Apple Inc., registered in the U.S. and other countries.
** Samsung is a registered trademark of Samsung Electronics Co., Ltd.

Minimum requirements for using the gestures via smartwatch are Apple Watch Series 4, Apple Watch SE (1st generation) or Apple Watch Ultra (1st generation) as well as Samsung Galaxy Watch 4.

20.2.6 Step Counter

The controller counts all steps that were taken with the leg with the orthosis in the different modes (Auto, Free and Lock). The step counter displays the strides taken for each respective mode. The sum of these values represents the total number of strides taken with the leg with the orthosis. Double the value for the total number of strides taken with both legs.

20.2.7 Battery Health

Through this menu item you can check the battery health. It can be "good", "average" or "poor". Depending on the battery health, the time until the next required charge may vary. With poor battery health, the controller must be replaced (see paragraph 22.2).

20.2.8 Cable Test

With this test, you can check the cable connection to the functional unit on the orthosis. For this test, put the orthosis on a workbench. Select the menu item **Cable Test** and follow the instructions in the app. You will then receive the results of the cable test for the functional unit.

When you start the cable test, the orthosis switches automatically into Lock mode and remains in this mode even after the test. To change the mode, use the remote control/**User** app or the **Expert** app.

20.2.8.1 Result Messages and Further Actions After the Cable Test

The following result messages will be displayed in the app:

Result Message	Meaning	Further Action
one system joint connected	The cable connection from the controller to the system joint is correct.	-
no system joint connected	The cable connection from the controller to the system joint is incorrect.	Check the cable connection from the controller to the system joint.
short circuit	There is a short circuit in the cable from the controller to the system joint.	Check the ports at the controller and the system joint.
C91: Call Technical Support	An internal device error has occurred.	Contact Technical Support.

20.2.9 Updating the Controller and Remote Control

When updating the app, the controller update and the remote control update, if available, are downloaded simultaneously. In the app you can update the desired controller or remote control by following the instructions in the app. Updating the remote control was successful if the LED on the remote control blinks green once.

Always update all controllers and remote controls in use.

The knee joint system must not be actively used during the update.

21. Advice on Optimal Orthosis Functionality

If problems occur with the orthosis, you can display a support code. You can then send this code to Technical Support so that the error can be corrected more quickly. You can find the support code in the app under the menu item “Information”.

21.1 Bluetooth® Connection

The connection quality depends on how interference-free your environment is.

21.2 System Knee Joint

Problem	Cause	Measure
The system joint does not unlock.	The proximal, posterior thigh band transfers flexion load when a leg is set back.	Shorten the upper edge of the thigh shell parallel to the gluteal fold, so that the gluteal muscles are unobstructed.
	The controller is adjusted for a **NEURO TRONIC** system knee joint.	In the **Expert** app menu, select the **NEURO HiTRONIC** system knee joint.
	The patient has an unusual gait.	With the **Expert** app, change the settings for unlocking in mid stance. The earlier the point in time is chosen, the easier the system joint unlocks. Then, the length of the period of stance phase control is shortened.
	The patient does not reach the dorsiflexion stop during heel lift due to short steps. Thus, the knee extension moment to unlock the system joint cannot be applied.	Check the alignment of the orthosis - on the workbench, - statically on the patient and - dynamically on the patient. Modify the alignment, if necessary.
	The forefoot lever of the foot piece does not achieve its knee-extending effect.	Check the orthosis' basic alignment. If the system ankle joint has a dynamic dorsiflexion stop, you might need to insert a stronger spring unit. Also, check the rigidity of the laminate.
	The patient makes unphysiological rotation movements inwards and outwards.	With the **Expert** app, change the setting for an easier unlocking.
	The plunger guide ring of the functional unit is unscrewed too far.	Adjust the plunger guide ring for the functional unit with a flat-head screwdriver, so that a small slit can be seen between the roll unit and the flexion stop disc while in extended position.
	The system joint is under flexion load.	The system joint must be brought in extension within two seconds of activating Free mode using the remote control/app. Otherwise, the app or the controller will indicate that the system joint is in Free mode, even though it remains mechanically locked. The system joint cannot be unlocked under flexion load.
	Fluctuations in air pressure and temperature can cause a pressure imbalance, resulting in the system joint remaining locked even though it has been unlocked electronically.	Press the rotary switch briefly to manually unlock the system joint.

Problem	Cause	Measure
The system joint switches unintentionally into Lock mode.	The battery was not charged.	Charge the battery.
	The orthosis undergoes strong shocks when it is set to Free or Auto mode.	Due to shocks, the magnetic field is interrupted and the orthosis locks automatically. Switch to another mode and then back to the desired one.
The system joint does not lock.	The plunger is stuck in the lower position.	Unscrew the screw of the plunger guide ring (fig. 28) slightly.
The system joint remains unlocked even if it is switched electronically to a different mode.	The rotary switch is unlocked.	Make sure that the rotary switch is set to the symbol.

21.3 Remote Control

Problem	Further Action
The controller does not respond to pressed buttons on the remote control.	Check whether the controller is still connected to the **Expert** or **User** app and whether the patient is standing still with the orthosis. If the problem remains, contact Technical Support.
The LEDs on the controller do not blink when pressing a button on the remote control.	

21.4 Controller

Problem	Further Action
When the MODE button is pressed, the LEDs do not light up.	Charge the battery. If the problem remains, contact Technical Support.
No devices are found during connection of the controller and the app.	Establish a connection between the app and controller within **30 seconds**. Check whether the LEDs light up or whether a short and a longer beep tone can be heard (see paragraph 19.2). If the problem remains, contact Technical Support.

22. Maintenance

Check the system joint regularly for wear and functionality. In particular, check the joint components listed in the following table for the possible problems described and, if necessary, take the appropriate measures. Also check the functionality after every maintenance carried out. It must be possible to move the system joint without problems or unusual noises. If you notice any play in the system joint in ap direction while in Lock mode, adjust the plunger guide ring (see paragraph 11.5, steps 8–11). Make sure that there is no lateral play.

Joint Component	Potential Problem	Measure	Recommended Inspection, Potential Replacement*	Latest Replacement
roll unit**	wear	replacing roll unit	every 6 months	every 6 months
air filter**	soiling	replacing air filter	every 6 months	every 6 months
guide piece	wear	replacing guide piece	every 6 months	every 6 months
pressure of the pneumatic spring	slow plunger movement	inflate pressure of the pneumatic spring (see paragraph 17)	every 6 months	every 6 months
flexion stop disc with sliding bushing	wear	replacing flexion stop disc	every 6 months	every 12 months
O-ring damper	wear	replacing O-ring damper	every 6 months	every 18 months
sliding washer	wear	replacing sliding washer, see paragraph 22.4	every 6 months	every 18 months
sliding bushing	wear	replacing sliding bushing	every 6 months	every 18 months
functional unit	wear or loss of function, see paragraph 22.3	replacing functional unit	every 6 months	every 36 months
countersunk flat head screw with hexalobular socket	wear	replacing countersunk flat head screw	every 6 months	every 36 months
bearing nut	wear	replacing bearing nut	every 6 months	every 36 months
cover plate	wear	replacing cover plate	every 6 months	every 36 months
remote control	outdated software	updating software	every 6 months	every 36 months
controller	outdated software	updating software	every 6 months	every 36 months
	poor battery health	replacing controller	every 6 months	every 36 months
extension stop	wear	replacing extension stop, see paragraph 11.3	every 6 months	if required
connection cable	damage	replacing connection cable	every 6 months	if required
software for mobile devices (operating system, **Expert** app, **User** app)	security gaps in the software	updating software	every 6 months	if required

* depending on the assessment of the distributor of the custom-made product regarding the patient's usage behaviour
** is part of the functional unit

Use the **maintenance set** for the initial maintenance after 6 months. The maintenance set is included in the scope of delivery of the system joint.

Before assembly, use LOCTITE® 7063 Super Clean to clean the threads of the joint's lower part and of the bearing nut. Allow the threads to air-dry for 10 minutes.

Secure the screws for the functional unit with the appropriate torque and LOCTITE® 243 medium strength during every maintenance (see paragraph 11.7). Remove all adhesive residues first.

You can find the individual maintenance plans for system joints in the download area (see QR code, fig. 47) on the FIOR & GENTZ website.

fig. 47

22.1 Documentation of Maintenance in the Orthosis Service Passport

The patient receives an orthosis service passport from a qualified specialist in orthopaedic technology when the orthosis is handed over (fig. 48). The orthosis must be checked regularly according to the specifications in the maintenance plan in order to maintain its function and to ensure the safety of the patient. The maintenance appointments are noted and confirmed in the orthosis service passport.

fig. 48

22.2 Checking the Battery Health

Regularly check the battery health of the controller with the **Expert** app. In the case of poor battery health or if the patient needs to charge the controller more than once per day, the controller must be replaced. Do not try to disassemble the controller as the battery is a fixed part of the controller.

Battery Health	Further Action
good	There is no need for action.
average	There is no need for action. You may need to replace the controller at the next maintenance.
poor	Replace the controller.

Poor battery health does not endanger the patient. It simply points out that the time until the next charge of the controller has been reduced.

22.3 Repair of the Functional Unit

A free repair of the functional unit within 36 months of purchase of the system joint (see invoice date) is included in the FIOR & GENTZ service. You will receive a replacement functional unit for the duration of the repair. To this end, please send us the functional unit, the filled-out claim form and the maintenance logs.

22.4 Replacing the Sliding Washers

Sliding washers are available in different thicknesses (e.g. GS2411-**040** is 0.40mm thick). Each thickness has a different marking (fig. 49). You will find the article numbers of the premounted sliding washers on the back page of these instructions for use.

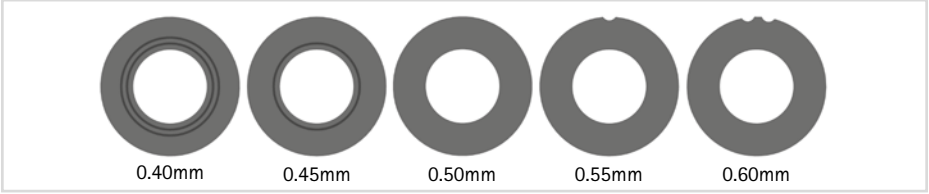


fig. 49

22.5 Replacing the Roll Unit

fig. 50

1 Demount the functional unit from the system joint.
2 Keep the plunger in place by gripping it from the slot with a 6.5mm double open-end wrench, and loosen the roll unit with a 13mm socket wrench insert with adapter (fig. 50).
3 Replace the roll unit.
4 Secure the screws with a torque of 2.5Nm.
5 Remount the functional unit onto the system joint.
6 Adjust the plunger guide ring as described in paragraph 11.5.

22.6 Dirt Removal

Dirt must be removed from the system joint and the controller when necessary and during regular maintenance. For this purpose, disassemble the system joint and demount the controller, and clean the soiled system components with a dry cloth.

23. Period of Use

To guarantee a safe use and complete functionality as well as an unlimited period of use of the system joints, you must adhere to the following conditions:

- Adhere to the specified maintenance intervals without interruption and document each maintenance (see paragraph 22).
- Adhere to the determined maintenance conditions (see paragraph 22).
- Check the wear parts, as required, and exchange them at the defined intervals (see paragraph 22).
- Check the adjustment of the system joint during maintenance and correct it if necessary (see paragraph 22).
- Check the functionality of the system joint during maintenance (see paragraph 22).
- The maximum load determined during the planning of the custom-made product shall not be exceeded by changes in the patient data (e.g. due to weight gain, growth or increased activity). If the determined maximum load on the system joint is exceeded, the system joint must no longer be used. When planning the custom-made product, expected changes in patient data need to be taken into account.
- The period of use of the system joints ends with the period of use of the custom-made product (orthosis).
- The multiple use of the system joint in another custom-made product is not allowed (see paragraph 30).

24. Storage

It is recommended to store the system joint in its original packaging until the custom-made product is produced. Heed the information regarding storage in paragraph 27.1.

25. Spare Parts

25.1 Exploded View Drawing **NEURO HiTRONIC**

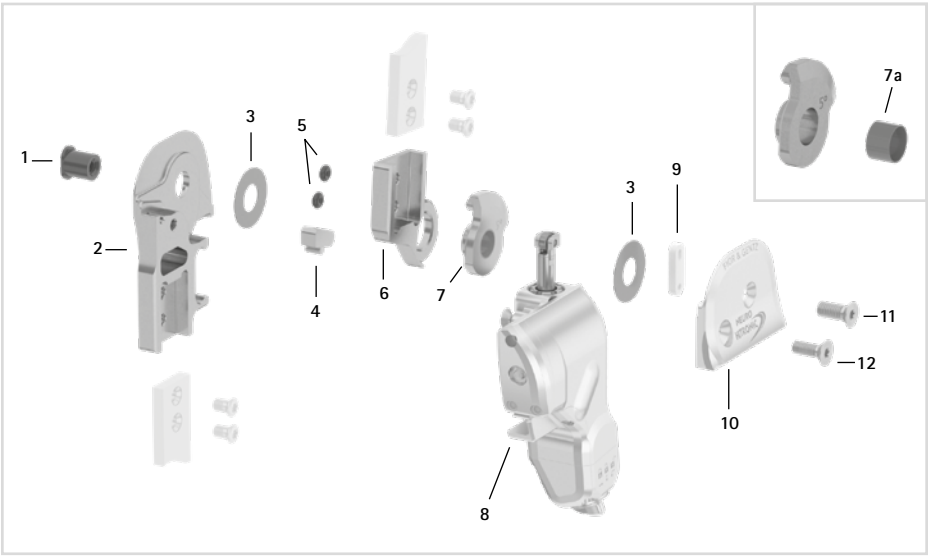


fig. 51

The functional unit is delivered preassembled. If individual components of the functional unit (fig. 52) have to be exchanged, you can order them as well.

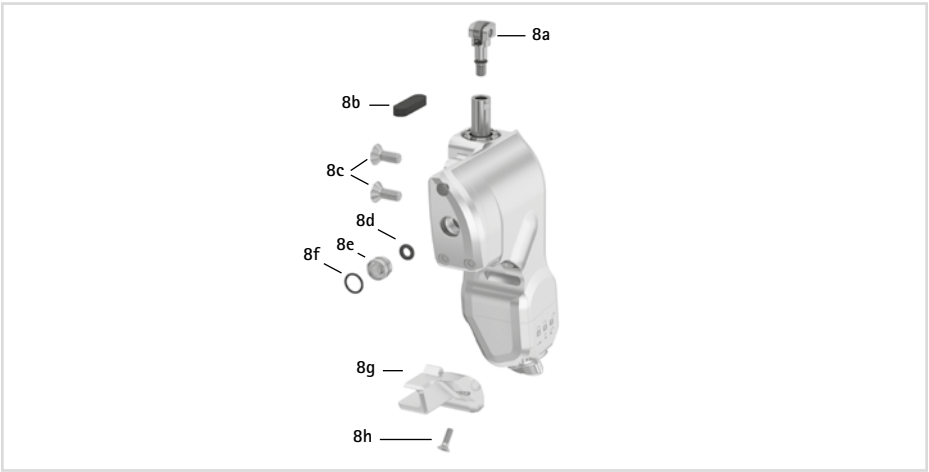


fig. 52

25.2 Spare Parts for the **NEURO HiTRONIC** System Knee Joint

Item	Article Number for System Width 20mm	Description
1	SB1069-L1110	bearing nut
2	SL0315-L/TI	lower part, left lateral, straight, titanium
2	SL0315-R/TI	lower part, right lateral, straight, titanium
3	GS2411-*	sliding washer*
4	SL9305-E005	5° extension stop
5	VE3771-D/012/026	O-ring damper set
6	SL0305-L/TI	upper part, left lateral, straight, titanium
6	SL0305-R/TI	upper part, right lateral, straight, titanium
7	SL0365-2L	5° flexion stop disc with sliding bushing, left lateral
7	SL0365-2R	5° flexion stop disc with sliding bushing, right lateral
7a	BP1211-L077	sliding bushing
8	SL3955-L	functional unit, left lateral
8	SL3955-R	functional unit, right lateral
8a	SL0355-11	roll unit
8b	SL0355-12	air filter
8c	SC1404-L10	countersunk flat head screw with hexalobular socket
8d	VE3771-030/15	O-ring
8e	SL0355-13	blind screw for valve
8f	VE3771-055/10	O-ring
8g	SL0355-16/L	cable cover, left lateral
8g	SL0355-16/R	cable cover, right lateral
8h	SC1403-L08/1	raised countersunk head screw with hexalobular socket
9	SL0355-01	guide piece
10	SL0355-L/AL	cover plate, left lateral
10	SL0355-R/AL	cover plate, right lateral
11	SC1406-L14	countersunk flat head screw with hexalobular socket (axle screw)
12	SC1405-L14	countersunk flat head screw with hexalobular socket

* Sliding Washers
Article Number for System Width 20mm
Ø = 24mm
GS2411-040
GS2411-045
GS2411-050
GS2411-055
GS2411-060

26. Disposal

Dispose of the system joint and its individual parts properly. The hydraulic oil contained in the functional unit must be disposed of through the appropriate collection points, observing the local regulations for the disposal of waste oil. Before disposal you must empty the oil from the functional unit. To do so, proceed as follows:

fig. 53

1 Press in the rotary switch and turn in the direction of the symbol.
2 Slowly unscrew the four screws in the functional unit a little.

Cover the exit point with a cloth as the oil might spurt out.

3 Press the plunger downward so that the oil drains out.
4 Unscrew the four screws completely (fig. 53) so that the rest of the oil drains out.

fig. 54

The product must not be disposed of with the residual waste (fig. 54). Please comply with the applicable national laws and local regulations for the proper recycling of recyclable materials.

The electronically controlled, automatic **NEURO HiTRONIC** system knee joint also falls under the area of application of the WEEE (Directive 2012/19/EU) of the European Parliament and the Council of 4 July 2012, regarding old electrical and electronic equipment.

For proper disposal, it is necessary to demount the system joint from the orthosis.

27. Technical Data

NEURO HiTRONIC	
period of use	unlimited, excluding wear parts (see paragraph 22)
protection type	IP44
operating mode	continuous operation

27.1 Ambient Conditions

Operation	
ambient temperature	-10°C – +40°C
	+5°C – +40°C when charging the battery, no exposure to direct sunlight
relative air humidity	0% – 95%, non-condensing air humidity
air pressure	1060mbar – 700mbar

Transport	
ambient temperature	-25°C – +60°C
relative air humidity	without original packing: max. 95%, non-condensing air humidity with original packing: max. 95%
air pressure	1060mbar – 700mbar

Storage	
ambient temperature	+5°C – +40°C, no exposure to direct sunlight
relative air humidity	max. 95%, non-condensing air humidity
air pressure	1060mbar – 700mbar

Data Transmission	
remote technology	Bluetooth Low Energy (BLE4.2)
working range	min. 2m
operating frequency	2.4GHz
frequency range	2400MHz – 2483.5MHz
nominal channel bandwidth	2MHz, 40 channels
modulation	GFSK
data rate (OTA)	1Mbps
output power	3.7dBm/2.344mW (less than 20mW)
maximum output power (EIRP)	4dBm

Power Supply Unit with Charging Cable (not Part of the Medical Device)	
article number	ET0780-01
manufacturer's designation	FW8002.1MUSB/05
ambient temperature in operation	0°C – +45°C
ambient temperature in storage	-40°C – +70°C
relative air humidity	10% – 90%rH
input voltage	100V – 240V (AC)
input frequency	50Hz – 60Hz
power	6W
output voltage	5V
output current	1400mA
Charging Cable (not Part of the Medical Device)	
article number	ET0710-01
length	1m

Controller Battery	
type	lithium-polymer battery
capacity	5Wh
operating time at room temperature and full battery charge at the end of three years of use	Auto mode: 26 000 strides/Free mode: 24 hours
behaviour of the system knee joint during the charging process	The system knee joint has no function.

User and Expert App	
supported operating systems	at least Android 6.0 or iOS 12
supported operating systems smartwatch	at least Wear OS 3.0 or watchOS 4.2

28. Signs and Symbols

CE labelling according to Regulation (EU) 2017/745 for medical devices

medical device

article number

Do not dispose of electronic devices with household waste. Dispose of the device and accessories at official delivery points for electronic devices.

manufacturer

batch code

serial number

protect from heat

keep dry

temperature limit values for storage/for transportation

air humidity limit values for storage/for transportation

air pressure limit values for storage/for transportation

follow the instructions for use (white on blue background)

single patient – multiple uses

IP44 protection from the ingress of solid foreign bodies (diameter ≥ 1.0mm) and from splashing water on all sides

UDI Unique Device Identifier – product identification number

Remote Control Type Plate

Controller Type Plate

29. CE Conformity

We declare that our medical devices as well as our accessories for medical devices are in conformity with the requirements of Regulation (EU) 2017/745. Therefore, the FIOR & GENTZ products bear the CE marking.

The product satisfies the requirements of the RoHS Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011, for limiting the use of specific hazardous substances in electrical and electronic equipment.

30. Legal Information

With the purchase of this product, our General Terms and Conditions of Business Transactions, Sales, Delivery and Payment will apply. The warranty expires, for example, if the product is mounted several times. Please note that the product is not supposed to be combined with other components or materials than with those recommended in the configuration result of the FIOR & GENTZ Orthosis Configurator. The combination of the product with products from other manufacturers is not permitted.

The information in these instructions for use is valid at the date of printing. The contained product information serves as guidelines. Subject to technical modifications.

All copy rights, particularly the distribution, copy and translation of these instructions for use or any part of them, must be authorised by FIOR & GENTZ Gesellschaft für Entwicklung und Vertrieb von orthopädietechnischen Systemen mbH. Reprints, copies and any other electronic reproduction, even partial, must be authorised in writing by FIOR & GENTZ Gesellschaft für Entwicklung und Vertrieb von orthopädietechnischen Systemen mbH.

31. Electromagnetic Compatibility

Special precautions must be taken for all electronic medical devices as regards electromagnetic compatibility (EMC). This device complies with standard IEC 60601-1-2:2022-01.

- All electronic medical devices must be installed and put into operation in compliance with the EMC-relevant information contained in these instructions for use.
- Portable and mobile RF communication devices may interfere with the performance of electronic medical devices.

The device satisfies all valid and required standards for electromagnetic disturbances.

- It generally has no effect on systems and devices found in its vicinity.
- It is generally not affected by systems and devices found in its vicinity.
- It is not safe to operate the device in the vicinity of high-frequency surgical devices.
- It is recommended that the device not be used in the direct vicinity of other devices.

31.1 Electromagnetic Environment

Operation of the device is allowed in the following electromagnetic environments:

- professional health care facilities (e.g. hospital, etc.)
- health care areas (e.g. use at home, use outdoors)

The patient must ensure that the device is exclusively operated in such environments.

31.2 Electromagnetic Emissions for all Devices and Systems

Usage Instructions and Manufacturer's Declaration – Electromagnetic Emissions

The product **NEURO HiTRONIC** is designed for operation in an electromagnetic environment as specified below. The customer or user of the product **NEURO HiTRONIC** must ensure that it is operated exclusively in such an environment.

Interference Measurements	Compliance	Usage Instructions for Electromagnetic Environment
RF emissions according to CISPR 11	group 1	The product **NEURO HiTRONIC** uses RF energy only for its internal function. Therefore, the RF emissions are very low and unlikely to cause any interference in nearby electronic devices.
RF emissions according to CISPR 11	class B	The product **NEURO HiTRONIC** is suitable for use outside of residential facilities. It is also suitable for facilities directly connected to a public low-voltage network that supplies residential buildings.
harmonics according to IEC 61000-3-2	class A	
voltage fluctuations/flicker according to IEC 61000-3-3	complies with requirements	

31.3 Electromagnetic Immunity for all Devices and Systems

Usage Instructions and Manufacturer's Declaration – Electromagnetic Immunity

The product **NEURO HiTRONIC** is designed for operation in an electromagnetic environment as specified below. The customer or user of the product **NEURO HiTRONIC** must ensure that it is operated exclusively in such an environment.

Immunity Test	Test Level IEC 60601	Compliance Level	Usage Instructions for Electromagnetic Environment
electrostatic discharge (ESD) according to IEC 61000-4-2	± 8kV discharge on contact ± 2kV, ± 4kV, ± 8kV, ± 15kV discharge through air	± 8kV discharge on contact ± 15kV discharge through air	Floors should be made of wood or concrete or be ceramic tiled. If the floor covering is made of synthetic material, the relative humidity must be at least 30%.
electrical fast transients/bursts according to IEC 61000-4-4	± 2kV for power supply lines 100kHz pulse repetition frequency	± 2kV for power supply lines	The quality of the supply voltage should be equivalent to that of a typical commercial or hospital environment.
surges according to IEC 61000-4-5	± 0.5kV, ± 1kV line-to-line voltage ± 0.5kV, ± 1kV line-to-ground voltage	± 1kV line-to-line voltage ± 1kV line-to-ground voltage	The quality of the supply voltage should be equivalent to that of a typical commercial or hospital environment.
voltage drops, short interruptions and fluctuations of the supply voltage according to IEC 61000-4-11	0% of U_T for 0.5 cycles and phase angles of 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 70% of U_T for 25/30 cycles and phase angles of 0° 0% of U_T for 250/300 cycles	0% of U_T for 0.5 cycles and phase angles of 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 70% of U_T for 25/30 cycles and phase angles of 0° 0% of U_T for 250/300 cycles	The quality of the supply voltage should be equivalent to that of a typical commercial or hospital environment.
magnetic field at mains frequency (50, 60Hz) according to IEC 61000-4-8	30A/m	30A/m	The magnetic fields at mains frequency should be equivalent to the typical levels of a commercial or hospital environment.
Note: U_T is the nominal voltage before applying the test levels.			

31.4 Electromagnetic Immunity for Non-Life-Supporting Devices and Systems

Usage Instructions and Manufacturer's Declaration – Electromagnetic Immunity

The product **NEURO HiTRONIC** is designed for operation in an electromagnetic environment as specified below. The customer or user of the product **NEURO HiTRONIC** must ensure that it is operated exclusively in such an environment.

Immunity Test	Test Level IEC 60601	Compliance Level	Usage Instructions for Electromagnetic Environment
conducted RF interference according to IEC 61000-4-6	$3V_{rms}$ 150kHz to 80MHz $6V_{rms}$ in ISM bands 150kHz to 80MHz	$3V_{rms}$ 150kHz to 80MHz $6V_{rms}$ in ISM bands 150kHz to 80MHz	Portable and mobile wireless devices should be used at a safety distance from the product **NEURO HiTRONIC** and its lines. The recommended safety distance was calculated using the equation applicable to the transmission frequency. Recommended safety distance: d = 1.2 √P d = 1.2 √P 80MHz to 800MHz d = 2.3 √P 800MHz to 2.7GHz P is the nominal output of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended safety distance in metres (m). According to an on-site investigation[a], the field strength of stationary radio transmitters should be below the compliance level at all frequencies. Interference may occur in the vicinity of devices marked with the following symbol:
radiated RF interference according to IEC 61000-4-3	10V/m 80MHz to 2.7GHz 80% AM 1kHz	10V/m 80MHz to 2.7GHz	

Note 1: the higher frequency range applies between 80MHz and 800MHz.
Note 2: these guidelines may not be applicable in all cases. The propagation of electromagnetic factors is affected by absorption and reflection from buildings, objects and people.

[a] The field strength of stationary RF transmitters such as base stations of radio telephones and mobile land radio equipment, amateur radio stations, AM and FM radio and television stations cannot be precisely determined in advance. A site survey is recommended to establish the electromagnetic environment as a result of stationary RF transmitters. If the field strength determined at the site of the product **NEURO HiTRONIC** exceeds the compliance level specified above, the product **NEURO HiTRONIC** has to be monitored with regard to normal operation during use. If unusual performance characteristics are noted, additional measures may be necessary, such as changing the orientation or site of the product **NEURO HiTRONIC**.

31.5 Electromagnetic Immunity to Proximity Magnetic Fields

Usage Instructions and Manufacturer's Declaration – Electromagnetic Immunity to Proximity Fields in the Frequency Range of 9kHz to 13.56MHz

The product **NEURO HiTRONIC** is designed for operation in an electromagnetic environment as specified below. The customer or user of the product **NEURO HiTRONIC** must ensure that it is operated exclusively in such an environment.

Immunity Test	Test Level IEC 60601	Compliance Level
proximity magnetic fields according to IEC 61000-4-39	30kHz[a], CW, 8A/m 134.2kHz, pulse modulation[b] 2.1kHz 65A/m_{rms} 13.56MHz, pulse modulation[b] 50kHz 7.5A/m_{rms}	30kHz[a], CW, 8A/m 134.2kHz, pulse modulation[b] 2.1kHz 65A/m_{rms} 13.56MHz, pulse modulation[b] 50kHz 7.5A/m_{rms}

[a] Applicable only to medical devices and systems intended for use in a home healthcare environment.
[b] The carrier must be modulated with a square wave signal with 50% duty cycle.

31.6 Recommended Safety Distances between Portable and Mobile RF Telecommunication Equipment and the Product **NEURO HiTRONIC** for Non-Life-Supporting Devices and Systems

Usage Instructions and Manufacturer's Declaration – Recommended Safety Distances between Portable and Mobile RF Telecommunication Equipment and the Product NEURO HiTRONIC

The product **NEURO HiTRONIC** is designed for operation in an electromagnetic environment where RF interference is monitored. The customer or user of the product **NEURO HiTRONIC** can help prevent electromagnetic interference by complying with the minimum distances between portable and mobile RF communication equipment (transmitters) and the product **NEURO HiTRONIC**, as specified below according to the maximum output of the communication equipment.

Nominal Output of the Transmitter [W]	Safety Distance [m] According to Transmission Frequency		
	150kHz to 80MHz $d = 1.2 \sqrt{P}$	80MHz to 800MHz $d = 1.2 \sqrt{P}$	800MHz to 2.5GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters whose maximum nominal output is not specified in the table above, the recommended safety distance d in metres (m) can be determined using the equation in the respective column, where P stands for the maximum nominal output of the transmitter in watts (W) according to the transmitter manufacturer.			
Note 1: the higher frequency range applies between 80MHz and 800MHz. Note 2: these guidelines may not be applicable in all cases. The propagation of electromagnetic factors is affected by absorption and reflection from buildings, objects and people.			

31.7 Test Specifications for the Immunity of Enclosures Against Wireless RF Telecommunication Equipment

Test Frequency [MHz]	Frequency Band[a] [MHz]	Radio Service[a]	Modulation[b]	Maximum Output [W]	Distance [m]	Immunity Test Level [V/m]
385	380 to 390	TETRA 400	pulse modulation[b] 18Hz	1.8	0.3	27
450	430 to 470	GMRS 460, FRS 460	FM[c] ± 5kHz deviation 1kHz sine	2	0.3	28
710	704 to 787	LTE band 13, 17	pulse modulation[b] 217Hz	0.2	0.3	9
745						
780						
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE band 5	pulse modulation[b] 18Hz	2	0.3	28
870						
930						
1720	1700 to 1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE band 1, 3, 4, 25, UMTS	pulse modulation[b] 217Hz	2	0.3	28
1845						
1970						
2450	2400 to 2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE band 7	pulse modulation[b] 217Hz	2	0.3	28
5240	5100 to 5800	WLAN 802.11 a/n	pulse modulation[b] 217Hz	0.2	0.3	9
5500						
5785						

Note: if necessary, the distance between the transmitting antenna and the ME device or ME system can be reduced to 1m to achieve the immunity test levels. The 1m test distance is permitted according to IEC 61000-4-3.

[a] For some radio services, only the frequencies for the radio link from the mobile communication device to the base station (uplink) have been included in the table.

[b] The carrier must be modulated with a square wave signal with 50% duty cycle.

[c] As an alternative to frequency modulation (FM), a pulse modulation of 50% at 18Hz can be used, as it does not correspond to the actual modulation, but is the worst case.

31.8 USA: FCC Regulatory Compliance Statement

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This device has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This device generates, uses and radiates radio frequency energy and, if not installed and used in accordance with the instructions for use, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this device does cause harmful interference to radio or television reception, which can be determined by turning the device off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the device and receiver.
- Connect the device into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

FCC Caution: Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this device.

31.9 Canada: ISED Regulatory Compliance Statement

This device complies with Industry Canada licence-exempt RSS standard(s).

Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

RSS-102 Statement:

This equipment complies with Industry Canada radiation exposure limits set forth for an uncontrolled environment.

CAN ICES-003(B)

32. Information for the Treatment Documentation

Add these instructions for use to your treatment documentation!

Patient Data

Name	
Address	
Postcode, City	
Home Telephone	
Telephone at Work	
Insurance	
Insurance No.	
Attending Physician	
Diagnosis	

33. Handing Over the Orthosis

The qualified specialist in orthopaedic technology made sure that the instructions for use for patients as well as the orthosis service passport were also handed over with the orthosis to the patient, parents or care team. By means of these instructions for use, the functions and handling of the orthosis were explained to the patient in detail. The next maintenance appointment was entered in the orthosis service passport. The patient was asked to bring the orthosis service passport along to every maintenance appointment.

Leg Side

☐ left ☐ right

Mounted Sliding Washers

1. GS _____ - _____

2. GS _____ - _____

PB2700-DE/GB-2026-04

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